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LEGAL AND ETHICAL ISSUES ARISING FROM THE USE OF EMERGING TECHNOLOGIES IN PAEDIATRIC TYPE 1 DIABETES

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Mobile health apps and wearable devices are widely available. They provide an opportunity to monitor and track health metrics continuously, and in real time, thus enabling diagnosis and chronic condition management to take place outside a hospital setting. The digital data produced can be shared with healthcare providers, researchers, and on social media. In this paper, we explore some of the legal and ethical challenges for doctors of these emerging technologies, by focusing on the example of management of childhood diabetes using continuous glucose monitors and insulin pumps. We identify and explicate these challenges through an analysis of three different case scenarios, all hypothetical but all realistic and reflective of current experiences of doctors caring for children with Type I diabetes. We argue that current legal and ethical approaches can effectively be applied in determining duties of healthcare professionals using emerging technologies, whilst recognising the significant change in the nature of the doctor-patient relationship and the perception of therapeutic benefit of some technologies.

I INTRODUCTION

This paper identifies the ethical and legal issues that arise in the management of children with Type 1 diabetes (T1D) when parents fit, and use, medical devices for their children without the support of their treating doctor. These situations arise because of recent advances in technologies for monitoring blood glucose levels and delivering insulin, coupled with the capacity for parents to buy devices direct from the supplier, rather than going through their child's doctor. They present significant challenges for clinicians involved in the care of the child, especially where parents seek assistance with using the device, despite the child's doctor having advised that it is not suitable for their child. We begin by providing some background about childhood diabetes and its usual management, and then describe some of the devices in question. Next, we set out three clinical scenarios and identify the legal and ethical questions which arise for the doctors involved. We draw on existing concepts in law and ethics to address these questions, but indicate where existing concepts might need to be extended to cover novel situations.

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II TYPE 1 DIABETES IN CHILDREN AND ITS MANAGEMENT

Type 1 diabetes (T1D) is a non-preventable, life-long, auto-immune condition that occurs when the pancreas does not produce insulin. It is most commonly diagnosed in children. In 2016, the Australian Institute of Health and Welfare reported that 6,386 children aged 0–14 had T1D.[1] T1D is a difficult condition to manage, necessitating a careful balance of diet, exercise, and insulin intake, with many children having suboptimal glycaemic control.[2] Insulin controls the amount of glucose circulating in the blood. Blood glucose levels that are poorly managed over an extended period of time can lead to a range of long-term health outcomes, including circulatory problems and retina damage. A sudden drop in blood glucose is a medical emergency (hypoglycaemia) requiring urgent treatment to avoid death.[3]

Children diagnosed with T1D require regular blood glucose testing, and regular injected doses of insulin to maintain blood glucose within safe limits. There are two main ways of doing this. The older technology involves putting a small drop of blood, taken from the finger using a lancing device, on a strip which is read by a small glucose monitor, and giving injections of insulin with a needle or a pen – done three to four times daily by the parents, under adult supervision at school, or by the child when old enough to do so. The new technology involves continuous glucose monitoring sensors (CGM) which have revolutionised glucose monitoring since the first prototype was introduced in 1999.[4] CGMs are wearable devices that measure glucose concentration almost continuously, at 1–5 minute sampling frequencies, thereby greatly increasing information on blood glucose levels. Clinical studies have shown improved diabetes management for adults.[5] The Australian Government is subsidising CGM sensors and transmitters for children and young people with T1D, aged under 21 years, who meet specific criteria.[6] The effects of CGMs are enhanced when used in conjunction with a compatible insulin pump.[7] Insulin pumps are increasingly used as an alternative to injecting insulin with a pen or needle, but they require more frequent contact with health professionals than is required for insulin injections.[8] In 2013, two in five children with T1D (43 per cent) used an insulin

[1] Australian Institute of Health and Welfare, Australian Government, *Diabetes Snapshot* (24 July 2018) <https://www.aihw.gov.au/reports/diabetes/diabetes-snapshot/contents/how-many-australians-have-diabetes/type-1-diabetes>.

[2] Maria E Craig et al, 'Predictors of Glycaemic Control and Hypoglycaemia in Children and Adolescents with Type 1 Diabetes from NSW and the ACT' (2002) 177(5) *Medical Journal of Australia* 235.

[3] *Diabetes in Australia* (2015) Diabetes Australia <https://www.diabetesaustralia.com.au/diabetes-in-australia>.

[4] Giacomo Cappon et al, 'Wearable Continuous Glucose Monitoring Sensors: A Revolution in Diabetes Treatment' (2017) 6(3) *Electronics* 65:1-16, 2.

[5] Nalani Haviland et al, 'Update on Clinical Utility of Continuous Glucose Monitoring in Type 1 Diabetes' (2016) 16(11) *Current Diabetes Reports* 115:1–7.

[6] National Diabetes Services Scheme (NDSS) and Diabetes Australia, *Continuous Glucose Monitoring* (2015) <https://www.ndss.com.au/cgm>.

[7] Noelle S Larson and Jordan E Pinsker, 'The Role of Continuous Glucose Monitoring in the Care of Children with Type 1 Diabetes' [2013] (1) *International Journal of Pediatric Endocrinology* 8:1–10.

[8] Australian Institute of Health and Welfare, *Insulin Pump Use in Australia* (Diabetes Series No 18, 2012) <https://www.aihw.gov.au/reports/heart-stroke-vascular-disease/insulin-pump-use-in-australia/contents/table-of-contents>.

pump to administer insulin, and they were more likely to be from higher socio-economic groups as the device is expensive to purchase and run.[9]

The most recent innovation in the use of these devices is to have CGMs that communicate directly with insulin pumps to automate insulin dosage in real time, rather than having doctors making decisions about dosage adjustment on the basis of accumulated past data from the CGM. Some one-way systems (for example the Medtronic 640G) will suspend insulin delivery when the CGM indicates glucose levels are low and the patient is approaching hypoglycaemia. Even more sophisticated is the emerging technology known as a hybrid 'closed loop system' (sometimes referred to as the 'artificial pancreas'), in which software with a control algorithm links the CGM to a compatible insulin pump so that subcutaneous insulin is delivered autonomously based on real-time glucose levels. The MiniMed 670G is currently the only hybrid closed-loop system licensed for commercial use. It has received approval by the Foods and Drugs Administration in the United States of America (US) but is not yet approved for supply in Australia, so cannot be recommended and fitted by doctors in Australia. The technology has been pushed even further in the US by parents of children with diabetes, who feel the medical device companies are being too slow and too conservative in their development of the software. These parents have pooled their expertise and resources to produce and continually update their own software, with the aim of making the closed loop systems maintain blood glucose levels that are more like normal physiological levels. Through platforms such as NightScout, under the banner #WeAreNotWaiting, parents of children with T1D can access this free open-source software to build their own closed-loop systems to control insulin delivery.

III Regulation of Devices Used for Diabetes Management

In Australia, CGMs and insulin pumps are regulated by the Therapeutic Goods Administration (TGA), part of the Department of Health. The TGA is responsible for ensuring that medical devices available for supply in Australia are safe and fit for their intended purpose.[10] A 'medical device' includes 'any instrument, apparatus, appliance ... *including the software necessary for its proper application* … to be used for human beings for … monitoring, treatment or alleviation of disease'.[11] Manufacturers and sponsors of glucose monitors, and insulin pumps are required to submit an application demonstrating that they have met the regulatory requirements of the TGA before the device can be lawfully supplied in Australia. It is then listed on the Australian Register of Therapeutic Goods (ARTG). The open-source non-commercial software described above has not been formally tested and is not approved for use in any jurisdiction. The medical devices which have been approved are vulnerable to being 'hacked' or appropriated with the open-source software to create a closed loop system that is outside regulatory mechanisms, has not been tested and has no evidence-base. The TGA

[9] Australian Institute of Health and Welfare, Australian Government, 'Prevalence of Type 1 Diabetes Among Children Aged 0-14 in Australia 2013' (Diabetes Series No 24, AIHW, 2015) <https://www.aihw.gov.au/getmedia/529ac141-4a43-49e0-958a-151094ef7ed9/18881.pdf.aspx?inline=true>.
[10] Department of Health, Australian Government, *Therapeutic Goods Administration* <https://www.tga.gov.au>.
[11] *Therapeutic Goods Act 1989* (Cth) s 41BD (emphasis added).

recognises that is has 'become an issue of real concern'[12] for which there is currently no solution.

IV Standard Diabetes Management

A typical arrangement for care of a child with T1D in Australia is management at home by his or her parent(s), with outpatient attendance every three months, and ongoing monitoring by a diabetes team in a hospital paediatric endocrinology department. If a CGM and insulin pump is being used, it will be supervised by the hospital as part of the child's ongoing care. Data produced by the CGM can be downloaded by parents in a format suitable for emailing to doctors, or it can be automatically uploaded to a Cloud site which doctors can access. The management plan requires parents to send data to the hospital team, to assist with management in between scheduled outpatient visits. Insulin doses may be adjusted by doctors on the basis of the data sent by parents. Diabetes nurse educators provide the child's parents with information and training on how to use the CGM, set the insulin pump to deliver the appropriate dosage of insulin, and advice on the circumstances in which levels of blood glucose appropriately trigger a call to the diabetes clinic at the hospital for advice. Anecdotally, a diabetes team at a tertiary paediatric hospital in a large Australian city may receive up to 50 telephone calls per day from parents reporting CGM readings with concerns and questions about managing insulin levels for their children.

In this standard situation, where the child is an outpatient and is being monitored at home using a CGM and insulin pump provided by the hospital, the legal and ethical duties of care owed by different members of the hospital diabetes team are straightforward. The treating clinicians have a duty to examine, diagnose, prescribe a course of treatment, and monitor the child.[13] If a CGM and insulin pump is recommended, the doctor has a duty to provide a full explanation to the parents of what the devices do, what their benefits and risks are, in order that parents can give informed consent to having their child's diabetes managed with these technologies.[14] The nurse educator has a duty to provide adequate training to the parents on how to use the device and when and how to seek assistance.

Our interest in this paper is in non-standard situations, where doctors encounter families using devices to manage diabetes in various ways that are outside the usual process. Using the example of Dr F and his team, we consider the legal and ethical issues raised by three hypothetical non-standard scenarios. Whilst these scenarios are hypothetical, they are all realistic and reflective of current experiences of paediatric endocrinologists in Australia. Non-standard uses of these new medical devices are important to consider, because they embody

[12] John Skerritt, 'The Medicines and Medical Devices Regulation Review and Other Regulatory Reforms' (Presentation, Therapeutic Goods Administration, AustMedtech, 24 May 2017) 26 <https://www.tga.gov.au/tga-presentation-ausmedtech-24-may-2017>.

[13] *Sidaway v Governors of Bethlem Royal Hospital* (1985) AC 871, 898 (Diplock L) noted a 'single comprehensive duty' covering diagnosis, treatment and the provision of information and advice.

[14] *Rogers v Whitaker* (1992) 175 CLR 479 and *Montgomery v Lanarkshire Health Board* [2015] 1 AC 14.

the realities of the introduction of new technologies into medicine. It is not necessarily a neat, orderly, controlled process; law and ethics need to be able to deal with this reality.

V NON-STANDARD DEVICE SCENARIOS

A *Request for Interpretation of Data from a Device, Outside an Existing Therapeutic Relationship*

Child A is 4 years old and has T1D. He was diagnosed at a tertiary hospital, X, and has received specialist input from the paediatric endocrinology team there. His diabetes is now managed at home by his parents, using a CGM, and the management plan is that they send data once a month to the diabetes nurse educator at hospital X, with monthly calls to check if dosage adjustments are required. The CGM sends readings to both parents' smart phones every 5 minutes, plus a daily and weekly graph, which they monitor closely. Child A's parents notice that a small number of readings are outside the recommended parameters, and contact the team at hospital X. They are told not to worry, but are not satisfied that the team have understood their concerns, or looked properly at all the data. So Child A's parents contact Dr F at hospital Y, which is in a different state, because he was recently in the media as an internationally renowned expert on use of CGMs in paediatric diabetes. They send all the CGM data from the last 2 months to Dr F, express concerns that A's glucose levels are sometimes too high, and request his advice on what they should do, since their local treating team has not addressed the problem properly. The email is labelled URGENT.

1 *Is Dr F under a Duty to Respond to the Parents of Child A?*

The model of care for diabetic children is highly organised and centralised, with care for each child provided by a specialist hospital in that child's home state; so Child A does not come within the catchment area for Dr F's team. Dr F has received a number of such emails and has developed a standard response, which is simply to direct the parents back to the team at hospital X for assistance, without looking at the data or commenting on their concerns. Is this a legally defensible and ethically justifiable response?

For the reasons detailed below, we argue that there is no legal duty upon Dr F to respond at all to unsolicited emails from parents of children who are not his patients. In ethical terms, Dr F's minimal response of directing the parents back to their treating doctor is appropriate, but Dr F has no ethical obligation to take any other action, and arguably has an obligation not to engage in the situation or offer advice.

Medical practitioners owe their patients a duty of care, but Child A is not an existing patient of Dr F. In *Lowns v Woods*,[15] Mahoney JA in the New South Wales Court of Appeal affirmed the view of the lower court that:

> In general the common law does not impose a duty to assist a person in peril even where it is foreseeable that the consequence of a failure to assist will be the injury or death of the person

[15] (1996) Aust Torts Reports ¶81-376.

> imperilled. ... It has been held in other common law jurisdictions that a doctor is under no duty to attend upon a person who is sick, even in an emergency, if that person is one with whom the doctor has not and never has been in a professional relationship of doctor and patient.[16]

There is no established duty of care between a doctor and a stranger, but the relationship between the parties may give rise to a duty of care in a particular case.[17] In *Lowns v Woods,* a duty of care based on the proximate relationship of the parties was established.[18] Proximity derives from the nexus of relationship between the parties. In *Lowns v Woods,* Badgery-Parker J (who first heard the case) considered that there was physical proximity between the doctor and Patrick, the child suffering from a prolonged epileptic fit, causal proximity (the doctor knew that the there was a major medical emergency calling for urgent attention) and circumstantial proximity (the doctor knew there would be serious consequences if the child was not treated). This case can be seen as an outlier, as proximity by itself is no longer endorsed as the unifying criterion,[19] and the case has not been broadly applied.

In the English case of *Caparo Industries plc v Dickman*,[20] the House of Lords set out a three-stage test to establish whether a duty of care is established: harm resulting from the conduct must be reasonably foreseeable; there is sufficient proximity between the parties; and it is fair, just, and reasonable to impose a duty of care. In Australia, the *Caparo* test was rejected in *Sullivan v Moody*.[21] Now, the High Court has adopted a methodology for analysing duty situations in novel scenarios. The courts will adopt a 'multifaceted inquiry' to determine whether a duty of care is established, which requires an examination of the foreseeability of risk, and identification of the salient features of a relationship.

The courts will first consider whether the type of relationship is one where it is reasonably foreseeable that the conduct or omission could cause harm to the vulnerable party. In *New South Wales v Godfrey & Godfrey*,[22] Spigelman CJ considered the test of foreseeability as 'undemanding';[23] and, in *Sullivan v Moody,* the Court described a foreseeable risk as one that was a 'real and not far-fetched possibility.'[24] If the email to Dr F included information that Child A had very high glucose levels and was marked URGENT, then it is reasonably foreseeable that failure to advise his parents to seek urgent medical attention would expose Child A to a risk of harm. A doctor working at a tertiary referral hospital, with expertise in paediatric endocrinology, has the experience and knowledge to make a connection between data and likelihood of harm.

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[16] Ibid 63, 166 (citations omitted), quoting Badgery-Parker J, the trial judge.
[17] The duty would be owed to Child A. For A's parents to exercise their parental responsibilities, Dr F and his team must include them in decision-making, and obtain informed consent from them.
[18] *Lowns v Woods* (1996) Aust Torts Reports ¶81-376, 63,175–63,176 (Cole JA).
[19] *Perre v Apand Pty Ltd* (1999) 198 CLR 180 (Gleeson CJ) 193–4 [9].
[20] [1990] UKHL 2; [1990] 2 AC 605.
[21] (2001) 207 CLR 562.
[22] (2004) Aust Torts Reports ¶81-741.
[23] Ibid 65, 661 [36].
[24] *Sullivan v Moody* (2001) 207 CLR 562, 576 [42].

2 *Salient Features Suggesting a Duty of Care*

However, foreseeability alone is not sufficient to establish a duty of care.[25] If healthcare professionals were under a legal duty to respond to all emails sent by non-patients requesting advice, then this would impose an intolerable burden of potential liability, and reduce the time available to care for current patients.[26] The courts have identified a number of 'salient features' which would determine the appropriateness of imposing a legal duty to take reasonable care to avoid harm or injury in novel situations.[27] The non-exhaustive list of salient features pointing towards a duty of care include: proximity between the parties; the vulnerability of the person harmed and their ability to protect themselves;[28] the healthcare professional's assumption of responsibility and control; the degree of reliance;[29] and knowledge of the likelihood of harm.

A doctor with expertise in diabetes could be expected to be aware of the likelihood of harm from high or low glucose readings, but Child A is not necessarily vulnerable to harm if Dr F does not respond to the email with advice. His treating doctors already know about the readings from the CGM and have decided that no action is required. Child A's parents could take him to the local emergency department, telephone the emergency services, or see their GP. There are realistic alternate pathways of support.

In *Agar v Hyde*,[30] the Court was reluctant to impose a positive duty to act on individuals who could not control the voluntary conduct of others. The risk of injury to Child A, if Dr F did not respond to the email, would be affected by a number of factors; most notably, whether the parents respond by seeking further medical attention – a factor beyond the influence of Dr F.

The proximity between the parties is one salient feature in attributing a legal duty. In *Sydney Water Corporation v Turano*,[31] the Court considered whether there was a 'sufficiently close and direct connection' between the parties for a duty of care to exist.[32] There is no physical, temporal, or pre-existing relational proximity between Dr F and Child A. The minimal reply from Dr F to A's parents to seek advice from their treating team at hospital X would not be enough in itself to establish the requisite connection. A doctor-patient relationship already exists with the team at hospital X, where he is already receiving care; where they are familiar with his history; and where they have a management plan in place. Imposing a duty of care on Dr F would result in two concurrent duties of care, with the same scope, leading to potential conflict in the therapeutic relationships, as well as confusion about responsibility for decision making.

[25] *Jaensch v Coffey* (1984) 155 CLR 549 (Gibbs CJ) 553–4.
[26] *Sullivan v Moody* (2001) 207 CLR 562, 576 [42].
[27] In *Caltex Refineries (Qld) Pty Ltd v Stavar* (2009) 75 NSWLR 649, 676 [103] (Allsop P).
[28] *Perre v Apand* (1999) 198 CLR 180.
[29] *Council of the Shire of Sutherland v Heyman* (1985) 157 CLR 424.
[30] *Agar v Hyde* (2000) 201 CLR 552.
[31] (2009) 239 CLR 51.
[32] Ibid 73 [53].

Recupero argues that,[33] in the US context, the courts may decide that a doctor's reply to an unsolicited email can establish a duty of care. In *Adams v Via Christi Regional Medical Center*,[34] the Court described a doctor-patient relationship as consensual. However, the jury was instructed that 'a physician-patient relationship may be created in any number of ways, including the act of a physician agreeing to give or giving advice to a patient in person or by telephone.'[35] Reliance is a salient feature which is considered in determining the existence of a duty of care. If Dr F went one step further and provided medical advice to Child A's parents, who relied upon the advice, then this may point towards a duty owed by Dr F.[36] He then leaves himself liable for a claim in negligence if he breached that duty, by a failure to follow up or provision of incorrect advice based on a lack of relevant information, and questions may arise whether his indemnity insurance would provide cover.

Health data produced by mobile apps and wearable devices can be transmitted via email to any healthcare practitioner whose details are publicly available. The number of parents who could contact Dr F for advice is considerable, although potentially limited to around 6,000 children in Australia who have type 1 diabetes.[37] Imposing a duty of care to respond to emails from parents of non-patients would limit the doctor's autonomy, and divert resources away from his current patients. In *ABC v St George's Healthcare NHS Trust*,[38] the Court of Appeal (England & Wales) acknowledged that there was a real concern that a flood of litigation might arise from imposing a duty in a novel situation.[39]

Thus, there is no legal obligation for Dr F to respond to the parents' email. However, doctors may sometimes have ethical obligations that go beyond the legal minimum. So are there considerations which would make Dr F ethically obliged to respond, even if he has no legal duty of care? A number of US studies have shown that about half of doctors who receive an unsolicited email asking for medical advice do respond.[40] Child A's parents are presumably genuinely concerned for his welfare, and are likely to be anxiously awaiting a response. Not receiving a response of any kind is likely to be distressing. Therefore, basic ethical considerations revolving around not causing (psychological) harm and showing respect for parents as the protectors, and medical decision-makers, for their child would suggest that some sort of response is ethically required. Yet, this does not suggest anything substantive about what the nature of the response should be. Even though a small proportion of the doctors in the two US studies cited above did reply with a suggested diagnosis and medical advice, we argue that it would be ethically unjustified for a doctor to make any clinical recommendations about the care of a someone who is not their patient. In this scenario, Dr F does not have access to

[33] Patricia Recupero 'Email and the Psychiatrist-Patient Relationship' (2005) 33(4) *Journal of the American Academy of Psychiatry and the Law* 465–75.
[34] *Adams v Via Christi Regional Medical Center*, 19 P 3d 132 (Kan 2001).
[35] Ibid [140].
[36] *Pyrenees Shire Council v Day* (1998) 192 CLR 330 [158] (Gummow J).
[37] Diabetes Australia <https://www.diabetesaustralia.com.au/>.
[38] [2017] EWCA Civ 336; [2017] Med LR 368.
[39] Ibid [45] (Irwin LJ).
[40] Stephen Borowitz and Jeremy Wyatt 'The Origin, Content, and Workload of E-mail Consultations' (1998) *JAMA* 280:1321–4; Gunther Eysenbach and Thomas Diepgen 'Responses to Unsolicited Patient E-mail Requests for Medical Advice on the World Wide Web' (1998) *JAMA* 280: 1333–5.

the child's medical history and has not examined him, so there is a considerable risk of error and harm to the patient in offering any clinical opinion. Further, Dr F should not intrude upon the existing therapeutic relationship between Child A's parents and their current doctors, because this could lead to confusion, mistrust, or conflict; all of which would make it harder for the current doctors to provide optimal care for Child A. So, Dr F's standard response of simply acknowledging the parents' concern, and then directing them back to their treating doctors, is the ethically appropriate one.

B *Wearable Device Provided by Third Party Healthcare Professional*

B is a 10-year-old boy with a 5-year history of T1D. Over that time, his diabetes has been poorly controlled despite multiple efforts at support from the hospital team. B and his parents should monitor B's blood glucose 4 times daily, using a lancing device to obtain a drop of blood, which is then inserted into a glucose monitor. In addition, B needs supervision with his daily insulin injections. B is infrequently supervised by his parents, and consequently misses both blood glucose testing and sometimes insulin injections, resulting in suboptimal glycaemic control. Dr F has had a number of discussions with B and his parents about this. B's parents say they are trying, but their lives are very busy and complicated, with both parents working casual jobs that involve variable shifts, so it is hard to establish any routine. At their most recent appointment, B's parents explain that they have been in contact with support groups online, and this has led them to request that Dr F fit the latest CGM and insulin pump for B. However, given B and his family's poor engagement with the tasks of self-care, Dr F and his team do not consider it safe or appropriate to provide such a system for B. The CGM and pump system still requires daily finger-pricks and input of information into the pump to make it work properly. There is risk that the pump will underdose or overdose if this is not done consistently and accurately.

B's parents are unhappy with Dr F's response and decide to go ahead and buy a CGM and sensor-augmented insulin pump anyway. They obtain a referral from their GP to a diabetes educator at a private hospital and have the pump and CGM supplied and fitted by this person. At the next appointment, Dr F is surprised and dismayed to see B wearing the pump and monitor. Dr F downloads the data from the pump, which shows that Child B is not interacting with his pump (ie not putting information into it) at all, and is not testing his blood glucose levels regularly. His HbA1C level is very high and indicates that his overall control has deteriorated significantly.[41] Nevertheless, his parents insist that they want to continue with the new equipment. B's clinical team are concerned about his worsening metabolic control and the imminent risk of acute complications, such as severe hypoglycaemia and diabetic ketoacidosis. These are potentially life-threatening events. Dr F has very strong reservations about the continuing care of B using the insulin pump and CGM, but is unsure what options are open to him that are legally and ethically acceptable. The nurse at the private hospital and the GP show no interest in continuing care, stating that B is a patient of Dr F and that he 'should deal with it'.

[41] HbA1c is a blood test that is used to help diagnose and monitor people with diabetes. It indicates how well diabetes has been controlled over the preceding 6–8 weeks. There is a greater risk of developing complications of diabetes with a higher HbA1c.

1 *Is there a Continuing Duty to Treat?*

This scenario challenges us to consider the legal and ethical duties owed by the private nurse educator who fitted the equipment, the GP and by Dr F, once the equipment has been fitted without his knowledge and against his advice. This raises the question of the standard of care by which each is judged.

The nurse fitting the device through private healthcare is in a proximate relationship with Child B and has assumed responsibility for his care. The relationship establishes a duty to exercise reasonable skill and care in providing and fitting an appropriate wearable device; in providing information and training to B's parents on use of the device; and in providing instructions about monitoring and follow up.[42] Arguably, the failure to obtain details from the child's treating endocrinologist, and to contact that doctor for a medical history and his/her opinion regarding the devices, falls below the peer professional standard by which this nurse would be judged to have acted appropriately in fulfilling her duty.[43] It seems unlikely that the nurse was acting in a way that would be widely accepted by a significant number of respected practitioners in the field and so would not meet the standard of care in fulfilling her duty of care. She has effectively washed her hands of any ongoing duties and tried to effect an end to the therapeutic relationship by sending B back to Dr F and his team. Termination of the duty of care is probably appropriate here as the nurse does not appear to be sufficiently qualified and experienced to provide good quality treatment for B and she has no interest in continuing care for him. For an effective termination of her duty of care, the nurse would have to ensure a proper hand over is made to Dr F and his team, after discussion with them, and make it clear to B's parents that she is no longer responsible for B's care. A registered nurse must meet the professional standards set out in the Code of Conduct for Nurses issued by the Nursing and Midwifery Board of Australia.[44] The Code states that a registered nurse must 'recognise when an activity is not within their scope of practice and refer people to another health practitioner when this is in the best interests of the person receiving care.'[45]

Dr F considers that treating B with the devices obtained by his parents puts B at risk of harm. Continuing to treat with the CGM and insulin pump challenges the ongoing duty of care provided by Dr F and his team. The content of the obligation owed by Dr F to B is to exercise reasonable skill and care in treating him, and advising his parents, and in doing so the doctor is expected to observe professional standards.[46] The question is whether Dr F is able to meet the standard of care if he acquiesces in continuing to oversee a form of treatment that he regards as risky. The *Bolam* case in England set the standard of care as that espoused by the profession itself;[47] namely, what a body of reasonable and responsible healthcare providers would do in

[42] *Rogers v Whitaker* (1992) 175 CLR 479, 493 (Gaudron J).

[43] This standard is adopted in most states. See, for eg, *Civil Liability Act 2002* (NSW) pt 1A div 6 s 50; *Civil Liability Act 2003* (Qld) s 22.

[44] Nursing and Midwifery Board of Australia, *Professional Standards* (reviewed 1 May 2018) <http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Professional-standards.aspx>.

[45] Ibid [2.2 f].

[46] *Breen v Williams* (1996) 186 CLR 71 [21] (Dawson & Toohey JJ).

[47] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 (QB).

that situation. In Australia, the seminal case of *Rogers v Whitaker* challenged the authority of the medical profession to set its own standard of care, at least with respect to the provision of information to obtain consent.[48] The standard of care 'is not determined solely or even primarily by reference to the practice followed or supported by a responsible body of opinion in the relevant profession or trade.'[49] In *Naxakis v Western General Hospital*,[50] the High Court clearly rejected the *Bolam* principle with respect to diagnosis and treatment.

Following the Ipp Panel Report,[51] every State and Territory made legislative changes to aspects of the doctrine of negligence developed at common law, including the standard by which health care professionals are judged. By way of example, the *Wrongs Act 1958* (Vic) provides that professionals are to be judged by peer professional opinion:

> A professional is not negligent in providing a professional service if it is established that the professional acted in a manner that (at the time the service was provided) was widely accepted in Australia by a significant number of respected practitioners in the field (peer professional opinion) as competent professional practice in the circumstances.[52]

There may be differing peer professional opinions widely accepted in Australia by a significant number of respected practitioners. However, the courts are the final arbiters of the standard to which a healthcare professional is to be judged and will determine what should be done, rather than what is done. Section 59(2) of the *Wrongs Act 1958* provides that 'peer professional opinion cannot be relied on … if the court determines that the opinion is unreasonable', whereas the NSW *Civil Liability Act 2002* uses the term 'irrational.'[53]

So, what is the standard of care in this situation? The issue is not with managing any child's diabetes with CGM and insulin pump, but rather continuing to manage it this way when B's blood glucose control has become significantly worse with this form of management. Dr F and his team may consider that the risk to Child B would be adequately managed if he and his parents were immediately provided with training and support, and given a timeframe in which to trial the devices, to see if they could keep the blood glucose levels under control. This would avoid the harm that might come from telling the parents to stop using the devices immediately– such as the family becoming disengaged with medical care.

Dr F and B's parents have differing views as to the form of diabetes management that is in B's best interests. Sub-optimal glucose control in diabetes is common, mostly due poor adherence

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[48] *Rogers v Whitaker* (1992) 175 CLR 479.
[49] Ibid 487 (footnote omitted).
[50] (1999) 197 CLR 269.
[51] Treasury, Parliament of Australia, *Review of the Law of Negligence: Final Report* (September 2002) <https://treasury.gov.au/review/review-of-the-law-of-negligence/> ('Ipp Panel Report').
[52] *Wrongs Act 1958* (Vic) s 59(1).
[53] *Civil Liability Act 2002* (NSW) pt 1A div 6 s 50(2). *Civil Liability Act 2003* (QLD) s 22(2) 'peer professional opinion cannot be relied on if the court considers that the opinion is irrational or contrary to a written law; *Civil Liability Act 2002* (WA) s 5PB an unreasonable practice may give rise to liability in negligence even if the practice conforms to widely accepted peer professional practice.

to the specified regimen of glucose testing and insulin dosing.[54] Doctors treating children with diabetes are very familiar with the need to accommodate and work with patients and families, taking into account their circumstances and trying to improve glucose control slowly over time. The courts have also identified this need for co-operation to facilitate treatment:

> Doctors nowadays recognise that their function is not a limited technical one of repairing or servicing a body. They are treating people in a real life context.[55]

In meeting the appropriate standard of care in this situation, in which B's blood glucose is not well controlled, Dr F must act in a way that is endorsed by a significant number of his peers. It may be that other paediatric endocrinologists would consider it acceptable practice to continue to treat Child B, using the wearable devices obtained by B's parents, *if* their use does not put him at undue risk of harm.

However, Dr F and the clinical team had previously decided not to provide a wearable device for B, because they felt that the level of engagement necessary to maintain safe glucose levels would not be achieved by him and his parents, thus putting him at risk of harm. Once B's parents went against this advice, this is exactly what did happen. The risk to B has already eventuated. Dr F has a duty of care to act in the best interests of B to ensure appropriate management of T1D. The Australian Medical Association's Code of Ethics states that doctors should '[c]onsider first the well-being of the patient'.[56] Poorly controlled blood glucose can lead to a hypoglycaemic reaction or ketoacidosis; both medical emergencies which, if left untreated, can be fatal. B's well-being is certainly compromised by his parent's insistence on using the wearable devices that they have purchased.

2 *Managing Ongoing Care*

If Dr F and the team think that B's parents are not fulfilling their parental responsibilities in acting in the child's best interests, then an application could be made to court for an order about treatment management. A parenting order, made under the Family Law Act 1975 (Cth) s 65C can include any aspect of care, welfare or development of the child. With similar effect the court may make an order in exercise of its *parens patriae* jurisdiction.[57] The paramount consideration is the promotion of the health or welfare of Child B.[58] The Court assumes parental responsibility, in part or in whole, in respect of the child and will 'interfere only to the minimum extent necessary, respecting the wishes of the child and the wishes of the parents.'[59] An appropriate order could be made that use of a CGM and insulin pump is not in B's best interests and that the parents present Child B to hospital for regular medical examination and assessment.

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[54] Joshua Borus and Lori Laffel, 'Adherence Challenges in the Management of Type 1 Diabetes in Adolescents: Prevention and Intervention' (2010) 22(4) *Current Opinion in Paediatrics* 405–11.
[55] *Re J (a Minor) (Wardship: Medical Treatment)* [1990] 3 All ER 930 [934] (Donaldson MR).
[56] Australian Medical Association, *AMA Code of Ethics 2004* (revised 2016) [2.1.1] ('AMA Code of Ethics').
[57] *TS & DS v Sydney Children's Hospital Network* ('Mohammed's case') [2012] NSWSC 1609
[58] *CAC v Secretary, Department of Family and Community Services* [2014] NSWSC 1855
[59] *Director-General, Department of Community Services; Re Jules* [2008] NSWSC 1193 [13] (Breton J).

It is not likely that Dr F would be compelled by a court order to treat Child B with the CGM if he properly exercised his judgment, after discussion with his clinical team and perhaps with reference to a clinical ethics advisory group, in determining it was not in B's best interests.

Taking legal steps to override parents' medical decisions for their children is an option that is always open to doctors, but there is an ethical question about whether this is an appropriate or justifiable course of action in any particular instance. This has been an issue of considerable debate in clinical ethics.[60] Such intervention, whether it is a report to Child Protection or seeking an order from the Family Court, can have significant negative consequences for the child, which must be taken into account.[61] Seeking a court order in relation to B's treatment will cause distress and disruption for the family, which will inevitably further affect blood glucose control; is it likely also to lead to major disruption of their trust in and relationship with Dr F and the diabetes team, whose care is essential for B's well-being. The decision to take legal steps is only ethically justified if the risks to B of continuing on the CMG and insulin pump are so great that they outweigh these risks to B of the legal action itself.[62] In this case, it is hard to see how legal intervention could be justified, because there is not an easy, one-off 'fix' for B's diabetes (in contrast, for example, to a blood transfusion for a child of Jehovah's Witness parents).[63] Maintaining a therapeutic long-term relationship is an essential part of the medical care.

Theoretically, another option for Dr F and team would be to simply end the therapeutic relationship, saying to B's parents that the hospital team cannot provide this form of care to B because it is so medically risky to him. If the parents won't stop using the device, they will have to find another doctor. However, this would seem inappropriate. The AMA Code of Ethics provides that there may be a 'need' to end a professional relationship if it has become ineffective or compromised.[64] B is only 10 years old and is reliant upon his parents to assist in managing his diabetic care. He is currently not competent to make healthcare decisions.[65] It would seem inappropriate for the paediatric endocrinology team at a tertiary hospital to end the professional relationship, when it is best-placed to provide expert care and support for B and his family. Finding 'another doctor' would not be a simple matter. Taking this option would have most of the detrimental effects of the legal intervention option described above, jeopardising B's well-being because of the behaviour of his parents. Therefore, Dr F and the team should again discuss with B's parents the risks posed by using the CGM and insulin pump and continue to support B and his parents to use finger prick blood tests and insulin injections.

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[60] Rosalind McDougall, Lauren Notini and Jessica Phillips. 'Conflicts between Parents and Health Professionals about a Child's Medical Treatment: Using Clinical Ethics Records to Find Gaps in the Bioethics Literature' (2015) 12(3) *Journal of Bioethical Inquiry* 1, 429–36; Rosalind McDougall, Clare Delany and Lynn Gillam (eds), *When Doctors and Parents Disagree: Ethics, Paediatrics and the Zone of Parental Discretion* (Federation Press, 2016).
[61] Lynn Gillam, 'The Zone of Parental Discretion: An Ethical Tool for Dealing with Disagreement between Parents and Doctors about Medical Treatment for a Child' (2015) 11(1) *Clinical Ethics* 1–8.
[62] Ibid.
[63] *An NHS Trust v Child B and Mr & Mrs B* [2014] EWHC 3486 (Fam)
[64] AMA Code of Ethics, above n 57 [2.1.12].
[65] He would not be considered 'Gillick' competent: see *Department of Health and Community Services v JWB & SMB* (1992) 175 CLR 218 ('*Marion's Case*').

C *Wearable Device Using Open-Source Software*

Child C is 5 years old and has T1D. He is under the care of Dr F and is receiving treatment as an outpatient. His parents are highly knowledgeable about his condition and are monitoring his glucose levels carefully. They have been provided with a CGM and insulin pump. In order to gain more control over the insulin dosage, and using open-source software from the website NightScout, they modify the algorithm settings which automate insulin delivery.[66] C's data can now be displayed on his parents' mobile phones, so they can tailor the amount of insulin that the pump delivers. The data from the monitor is also sent wirelessly in real time to the pump, so that the insulin dose can be adjusted accordingly, using algorithms in the software they have downloaded, without any need for human intervention.

Dr F discovers this modification to the device when he reads the monthly data download from the insulin pump at the out-patient appointment. He feels very uncomfortable. Currently, the Food and Drug Administration in the US has approved only one hybrid closed-loop system, specific to patients who are 14 years and older with type 1 diabetes. No closed-loop systems have been approved for use in Australia. This system that C's parents have created using the open-source software is not tested or approved anywhere. Overseeing the treatment of C with this system is problematic for Dr F, because he has no knowledge of the algorithms in the software, and cannot vouch for the integrity of the system. It may work very well, or it may suddenly go catastrophically wrong; Dr F has no way of knowing.

In this section, we consider the legal and ethical obligations of Dr F to continue to treat C with a wearable device which incorporates software that is not regulated by the TGA.

1 *Parental Responsibility*

With increasing reliance upon the internet as a source of information on health and disease, it is to be expected that parents will access information on novel and experimental treatment options. This may lead to concerns that the treatment currently offered by their healthcare practitioner is not the latest or best. Adults with T1D have reported increased control over their glucose levels using a closed-loop system:

> I feel a huge difference … I don't have to be constantly wondering how much insulin to take, or always checking my glucose level. [The] algorithm beeps me if I have to do something. And my time in the proper range has gone from around 60 percent to nearly 90 percent. It's amazing.[67]

Respect for the autonomous healthcare decisions of adults is the accepted standard in medical ethics. If an adult who is mentally competent and is well-informed makes decisions about health care which put him or herself at some risk, this is within their rights, and it would not be ethically justifiable for a doctor to attempt to override this decision or coerce the patient to act

[66] Nightscout, *NIGHTSCOUT: #WeAreNotWaiting* (2018) <http://www.nightscout.info/>.
[67] Dan Hurley, 'Diabetes Patients are Hacking their Way Toward a Bionic Pancreas', *WIRED* (online), 24 December 2014 <https://www.wired.com/2014/12/diabetes-patients-hacking-together-diy-bionic-pancreases/>.

differently.[68] So, a strong ethical case can be made for doctors to co-operate with adults who chose to use DIY closed loop systems, provided only that they have informed the patient about the lack of evidence, testing and regulation, and the consequent risks involved. However, the situation is different with children, both ethically and legally. Those with 'parental responsibility' have duties, powers, and responsibilities in relation to their children, which include the authority to make decisions about medical treatment.[69] However, such authority is legally not unfettered and is limited to decisions that are in their child's best interests. Although the term, 'best interests', may be 'imprecise'[70] and lacking a hierarchy of values,[71] legislation and case law provide relevant factors to assist in determining the best interests of children. Section 60CC of the *Family Law Act 1975* (Cth) states the primary considerations of the court in determining best interests of the child: 'the benefit to the child of having a meaningful relationship with both … parents; and the need to protect the child from physical or psychological harm' and identifies additional considerations, without specific application to healthcare decisions.

In the English case of *Re MB*,[72] which concerned the treatment of a baby with spinal muscular atrophy, the term 'best interests' was used in the widest sense to include 'every kind of consideration capable of impacting on the decision. These include, non-exhaustively, medical, emotional, sensory (pleasure, pain and suffering) and instinctive (the human instinct to survive) considerations'.[73] The concept of a balance sheet has been utilised, in the sense of identifying the benefits and harms of treatment options. The Supreme Court of Queensland in *Hospital v T*,[74] considered the concepts of sanctity of life and the best interests of a young person. Although treatments which preserve life weigh heavily in a balance sheet, this is not at the expense of the child's ongoing quality of life.

There may be a reasonable disagreement between a clinical team and parents about what treatment is in the child's best interests, especially in the context of novel or experimental treatments. In the English case of *Re SR*,[75] the mother of a 7-year-old boy with a brain tumour refused to consent to conventional chemotherapy and radiotherapy. Her view, that alternative therapy would be in the child's best interests, was not accepted by the Court, as she was unable to produce any evidence of their effectiveness. On this point, Bodey J stated:

> To have any realistic prospect of becoming selected by the court … the proposed plan would have to have a prognosis as to probable survival rate not much less than (and preferably equal to) the sort of survival rate achievable through the use of the orthodox treatment universally applied at present by oncologists in this country.[76]

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[68] *Re B (adult: refusal of medical treatment)* [2002] 2 All ER 449
[69] *Family Law Act 1975* (Cth) s 61B.
[70] *Marion's Case* (1992) 175 CLR 218, 259–60.
[71] Ibid 270.
[72] *An NHS Trust v MB* [2006] 2 FLR 319 ('*Re MB*').
[73] Ibid [16] (Holman J). See also *Wyatt v Portsmouth Hospital NHS Trust* [2006] 1 FLR 554 [87] (Wall LJ).
[74] [2015] QSC 185.
[75] *An NHS Trust v SR* [2013] 1 FLR 1297 ('*Re SR*').
[76] Ibid [25].

Child C's parents may argue that they are promoting his best interests, and that a closed loop system supported by open-source software more effectively manages his T1D than the conventional device system. There is a lack of evidence to support this assertion about the closed loop system, but in general terms, they are taking a medically orthodox approach which has a very solid evidence base – use of insulin to control levels of blood glucose. Their preferred option is not alternative therapy, as it was in *SR*. In contrast to the scenario of B discussed above, C's parents do not appear to be putting the health of C at risk as they are monitoring C's blood glucose levels carefully, are diligent in the care of their child, and very focused on achieving best possible management. In *Re King (A Child)*,[77] the parents of 5-year-old Ashya were very unhappy with aspects of the hospital treatment plan, which included radiotherapy. They asked the hospital to consider using a new type of radiotherapy known as proton therapy. The Court recognised the reasonableness and value of the parents' view, with Baker J observing:

> In some cases, this court is faced with a dispute between medical authorities and parents who are insisting on a wholly unreasonable course of treatment, or withholding consent to an essential therapy for their child — for example, a blood transfusion. This is manifestly not such a case. The course of treatment proposed by Mr and Mrs King is entirely reasonable. Ashya has a serious medical condition. Any parents in the position of Mr and Mrs King would do whatever they could to explore all options. Some parents would follow the advice of the local doctors to use conventional radiotherapy, others would prefer the relatively untested option of proton therapy (assuming the funds can be made available to meet the cost of transport and treatment) in the hope that the toxic effects of radiation will be reduced. Both courses are reasonable and it is the parents who bear the heavy responsibility of making the decision. It is no business of this court, or any other public authority, to interfere with their decision.[78]

In ethical terms, it would appear that the decision of C's parents to use the unapproved closed-loop system falls within the Zone of Parental Discretion - parents' decisions should only be overridden if the child is likely to suffer significant harm.[79] It would not be ethically justified to seek to override it, either by going to court or by seeking to pressure the parents in some way.

2 *The Duty of Care Owed by Dr F and his Team*

Child C's parents may not be putting him at risk if they continue to use the devices with the open-source software, as they have demonstrated vigilance in keeping his glucose levels within safe margins. Dr F and the paediatric endocrinology team will have discharged their duty of care by discussing the risks of using the devices now modified with the software, and the impact

[77] [2014] 2 FLR 855.
[78] Ibid [34].
[79] Gillam, above n 62, 1–8.

on the effectiveness of care that can be provided by them, which should be clearly documented.[80]

Nevertheless, could it be argued that Dr F and the paediatric endocrinology team are not under a duty to *continue to* treat C with the system now used by the parents? In doing so, the clinical team is effectively condoning the use of software which renders the wearable device untried and unregulated. Using this unapproved system could be seen as going beyond what B's parents did in having a CGM and insulin pump fitted against medical advice. At least those devices have been tested and approved, are supported by an evidence-base and recognised manufacturer. In contrast, the software used to network devices for T1D is outside any peer review or external validation system. Additionally, Dr F would not be able to fulfil his duty to obtain informed consent from C's parents for the treatment regime that C is undergoing. Dr F is required to provide information about the material risks of treatment.[81] A paediatric endocrinologist would be expected to keep abreast of developments in the field; to be aware of clinical trials, systematic reviews, and TGA reviews of medical devices, but it would be going beyond the scope of his duty to know of and provide information about open-source software. In this regard, the parents' use of open-source software is rather similar to parents using alternative therapies (eg homeopathy or Chinese traditional medicine) in conjunction with conventional biomedical treatments for a child with cancer. Oncologists cannot be expected to have detailed knowledge of alternative therapies and their possible risks and interactions with conventional drugs. The best that a doctor can do is warn parents about the unknowns.

Despite these difficulties, it is hard to see how Dr F would be ethically justified in refusing to continue to provide care for Child C, for the reasons outlined above in relation to Child B. Tolerance of patients' and parents' use of non-evidence-based alternative therapies is an accepted approach in medical practice, so it could be argued that, in legal terms, Dr F's co-operation with Child C's parents in using the open-source software would constitute an approach that would be endorsed by his peers, and hence would meet the standard of care required, as discussed above. Ethically, working with these parents rather than against them is likely to be the best way to promote Child C's well-being in the long-term. There seems very little basis for a Child Protection notification or a seeking a court order about treatment, because the risk to Child C, whose parents are fully engaged and carefully monitor blood glucose levels, is probably much lower than the risks to Child B of poorly monitored use of approved devices.

VI Conclusion

In this paper, we have explored legal and ethical implications of emerging technologies for management of childhood diabetes, using established principles and concepts. We have used these principles and concepts to make a case for what would be acceptable practice in three scenarios. In doing so, we have extended their application or stretched their interpretation.

[80] If adequately informed of the risks by Dr F, C's parents could be said to have assumed the risk of using the devices.

[81] The standard of disclosure was set out in *Rogers v Whitaker* (1992) 175 CLR 479.

Novel medical technologies often prompt claims that novel legal and ethical approaches are needed, but the need is not immediately obvious here. The interesting question is whether extension of current legal and ethical concepts will continue to be viable as the nature of the doctor-patient relationship undergoes significant change. Patients and their parents are increasingly driving and seeking to control medical treatment,[82] not because of new medical technologies, but rather because information and communication technologies have given them access to knowledge previously only available to doctors. As this change in the dynamic of the therapeutic relationship becomes stronger and more widespread, it will be interesting to see whether concepts such as informed consent and standard of care determined in reference to what other doctors do, continue to be meaningful.

[82] Nancy Calabratta, 'Consumer-Driven, Patient-Centered Health Care in the Age of Electronic Information' (2002) 90(1) *Journal of the Medical Library Association* 32–7.